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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,554	12/05/2003	Kuniharu Hamazaki	246134US-3 DIV	7981
22850	7590	04/04/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			VENIAMINOV, NIKITA R	
		ART UNIT	PAPER NUMBER	3736

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/727,554	HAMAZAKI, KUNIHARU	
	Examiner	Art Unit	
	Nikita R Veniaminov	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 December 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,4 and 7-15 is/are rejected.
- 7) Claim(s) 2,3,5 and 6 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 December 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 10/013,366.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/05/2003</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the Invention of Group I in the reply filed on 12/30/2004 is acknowledged. The traversal is on the ground(s) that Group II is a combination including Claim 7 that recites each feature of the independent claim in Group I. Claims 4-6 are subcombination claims like Claims 1-3 are subcombination claims, Claims 4-6 include all the subject matter of Claims 1-3. This is found persuasive. The Restriction Requirement has been withdrawn.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 12/05/2003 was considered by the examiner.

Claim Objections

3. **Claim 4** is objected to because it includes reference character in line15, which is not enclosed within parentheses.

Reference characters corresponding to elements recited in the detailed description of the drawings and used in conjunction with the recitation of the same element or group of elements in the claims should be enclosed within

parentheses so as to avoid confusion with other numbers or characters which may appear in the claims. See MPEP § 608.01(m).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 12 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Schmidt (US 2003/0036673).** Schmidt ('6673) teaches a therapeutic material device comprising
(Claim 12 independent) outer needle having an outer tubular needle (10) and an outer needle hub (14) supporting the outer tubular needle (10), a middle needle having a middle tubular needle (28) and a middle needle hub (36) supporting the middle tubular needle (28) and an inner needle having a solid needle (32) and an inner needle hub (34) supporting the solid needle (32), wherein said outer needle (10), said middle needle (28) and said inner needle (32) are being to be connected for use.

(Claim 15) The therapeutic material delivery device as recited in claim 12, wherein said outer tubular needle (10), said middle tubular needle (28) and said

solid needle (32) are formed such that said solid needle (32) has a largest length, that said middle tubular needle (28) has an intermediate length and that said outer tubular needle (10) has a smallest length (Figure 4).

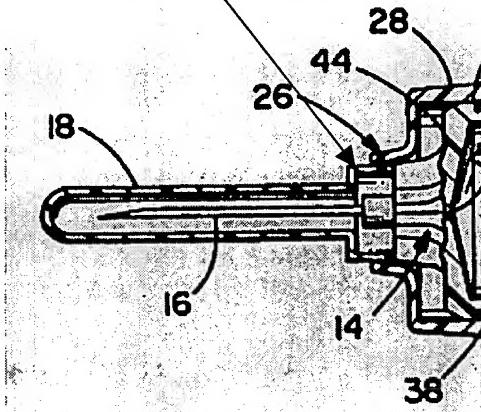
Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 13 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 2003/0036673) as applied to claim 12 above, in view of Ryan (US 5,059,185) cited by Applicant. Schmidt ('6673) teaches a therapeutic material device, as described in paragraph 5 above, but he does not teach an outer needle capped with a sheath for protection of a forward end of said outer needle, wherein said sheath has a projection formed on inner circumference base portion thereof.

Ryan ('185) teaches a syringe having an outer needle (16) capped with a sheath (18), which has a projection formed on an inner circumference base portion thereof.



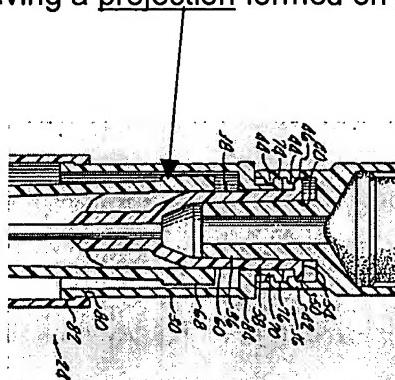
It would have been obvious to one of ordinary skill in the art at the time of the invention to use the sheath of Ryan ('185) to cover the outer needle of Schmidt ('6673) to keep the outer needle in sterilized condition, or to protect the person's fingers from accidental needle-stick injuries.

8. **Claims 1, 4 and 7-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 2003/0036673) in view of Martell (US 4,897,083). Schmidt ('6673) teaches a therapeutic material device comprising an outer needle having an outer tubular needle (10) and an outer needle hub (14) supporting the outer tubular needle (10), a middle needle having a middle tubular needle (28) and a middle needle hub (36) supporting the middle tubular needle (28) and an inner needle having a solid needle (32) and an inner needle hub (34) supporting the solid needle (32), wherein said outer needle (10), said middle

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needle (28) and said inner needle (32) are being to be connected for use, but he does not teach a cover formed of a plurality of tubes having different diameters that are formed so as to consecutively decrease from a forward place to an outer needle hub in a backward place, and said tubes are thereby connected such that the cover is extendable in the longitudinal direction; and an outer needle capped with a sheath for protection of a forward end of said outer needle.

Martell ('083) teaches a cover (24) formed of a plurality of tubes (30, 32 and 34) having different diameters that are formed so as to consecutively decrease from a forward place to an outer needle hub (18) in a backward place, and said tubes (30, 32 and 34) are thereby connected such that the cover (24) is extendable in the longitudinal direction (Figures 4 and 5); and a sheath (22) for protection of said forward end, having a projection formed on an inner-circumference base portion.



It would have been obvious to one of ordinary skill in the art at the time of the invention to use the cover of Martell ('083) with the device of Schmidt ('6673) to provide telescopic extending for full protection for the needle assembly, and to

keep the outer needle in sterilized condition, or to protect the person's fingers from accidental needle-stick injuries, as taught by Martell ('083).

Allowable Subject Matter

9. **Claims 2, 3, 5 and 6** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
10. The following is a statement of reasons for the indication of allowable subject matter:

None of the prior art, either alone or in combination, teaches or suggests a protective tool for a therapeutic material delivery device, as claimed, wherein a cap has an inner tube formed inside, said inner tube has, made in a bottom thereof, a hole for inserting and passing an outer tubular needle, and said inner tube has, formed in an outer circumference, a groove portion for inserting a forward end of said outer tubular needle; and wherein a stopper is constituted of a tubular opening/closing portion having a forward end and a connector portion, said opening/closing portion has slits formed in the longitudinal direction, one in an upper portion and the other in a lower portion, said forward end has an opening portion; and said connector portion has pressing portions formed, one on the right and the other on the left, and has cutout grooves formed, one in an upper place and the other in a lower place.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hamazaki et al. ('037) ; Coffey et al. ('198) ; Rolland et al. ('427) ; Mercereau et al. ('937) ; Belef et al. ('3808) and Reed et al. ('8854).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (571) 272-4735. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nikita R Veniaminov
Examiner
Art Unit 3736

March 25, 2005.



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